

**REMARKS/ARGUMENTS**

**Note to the Examiner:** Applicant's agent contacted Examiner Evelyn Huang, the primary Examiner of this application, in order to obtain guidance with respect to the Office Action mailed June 21, 2005. However, Examiner Huang advised the Agent that she no longer works on this file and instructed the Agent to contact the Examiner's supervisor, Cecilia Tsang at 571-272-0562. However, on more than two occasions, the Applicant's Agent was not able to find the supervisor but left voice messages for which no response was provided.

Claims 1 to 13 remain in the Application. Applicant has amended Claims 1, 3, 9 and 13. No new subject matter has been added.

The Examiner has rejected Claims 9 and 13 under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner purports that in the absence of a definition of the "equivalent" of toluene, it is unclear whether it refers to solvents with the same melting point as toluene or compounds having similar electronic configurations as toluene, etc. Applicant has amended Claims 9 and 13 by deleting the passages which the Examiner has indicated causes a rejection under 35 U.S.C. 112, second paragraph.

It is to be noted that Applicant mended these claims in order to advance the prosecution of the Application and the amendment should not be taken as a concession by Applicant to the Examiner's position. Applicant maintains the position that the person skilled in the art would know what the terms in the claims would mean and the invention is fully enabled by the examples disclosed therein such that the person skilled in the art would know what the "toluene equivalents"

would be applicable to the reaction spelled out in the application. Applicant respectfully directs the Examiner to the response filed by Applicant previously addressing the issues of toluene and equivalents thereof.

Furthermore, the Examiner has also rejected claims 1 through 13 inclusive under 35 U.S.C. 112, first paragraph as enunciated in Examiner's Office Action found at page 2 through 4, points (a) through (f). In this respect, Applicant submits the following.

The use of TMSI as a reducing agent, the amounts of TMSI and temperature conditions thereof were well known to a person skilled in the art at the date of filing of this application. Exemplary of said teaching can be found in the Tetrahedron reference cited at page 5, paragraph 9 of Applicant's application as filed. This reference and the teachings thereof are incorporated by reference in this application. This reference was included in the Summary of Invention section of the application.

This reference clearly provides that at least 2.0 equivalents of TMSI is required when used as a reducing agent. Furthermore, at page 11057 of this reference there is taught the use of TMSI at 4.64 equivalents. Thus, a person skilled in the art in reading Stoner would know the amount of TMSI to use as a reducing agent, (minimum of two equivalents) and the greater the amount of TMSI the faster the reaction will occur. Similarly, as can be found in Stoner the temperature is provided to be in the 0 to 20°C range. Applicant's examples provide reaction temperature of 0 to 5°C when TMSI is being added. This is in line with the Stoner reference. This would be a teaching that would be known to a person skilled in the art, namely a chemist, with respect to the amount and with the temperature range, when using TMSI.

Another article which provides guidance to the amount, and provided for the Examiner's reference, is a 1992 article in Sulfur Letters, page 269-273 which provides for the use of TMSI as reducing agent and one can see at page 270 the ratio of chlorotrimethylsilane (TMSI) to the alcohol is 36 mmol to 6 mmol, which in essence means that TMSI is 6 equivalents used in the reaction for the reduction. This is consistent with the Stoner teaching and this is consistent with our teaching and what a person skilled in the art would know and interpret the teachings of Applicant's application and examples thereof. Furthermore, the Examiner is reminded of the following,

As stated by the Federal Circuit:

When rejecting a claim under the enablement requirement of Section 112, the "Patent Office" bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. (See *In re Wright* 999 F.2d 1557, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

Furthermore, as stated *In re Moore* 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971), the CCPA summarized the general requirements for enabling disclosure:

The relevant inquiry may be summed up as being whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims.

Furthermore, as stated by the C.C.P.A. *In re Angstadt*, 537 F.2d 498, 190 USPQ 214, 219 (C.C.P.A. 1976):

We note that the PTO has the burden of giving reasons, supported by the record as a whole, why the specification is not enabling ... Showing that the disclosure entails undue experimentation is part of the PTO's initial burden ...

The enablement requirement, however, does not require that the Applicant disclose the invention in a manner that can be understood by everyone. If such were the case patent applications would be long, unfocussed documents. The CCPA has also stated that

"not every last detail is to be described, else patent specifications would turn into production specifications which they were never intended to be" (see *In re Gay*, 309 F.2d 769, 135 USPQ 311, 316 (C.C.P.A. 1962).

Furthermore, the public would also likely have difficulty in determining the new or important aspects of the invention since the issued patent would contain much extraneous information. Rather, for an application to be enabling it must explain how to make and use an invention to one of ordinary skill in the art. Again, the person of ordinary skill is fictitious. The Federal Circuit has also commented:

The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is not determinative. The factors that may be considered in determining level of skill include type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology and educational level of active workers in the field. Not all such factors may be present in every case and one or more of them may predominate. (See *Custom Accessories Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986))

Thus, "it is irrelevant whether the specification explains how to make and use the invention using broad terminology or illustrative examples." (See *In re Wright*, 9999 F.2d 1557, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Therefore Applicant respectfully submits that a person skilled in the art would know how to carry out the claimed invention and would know all the known amounts of TMSI and temperature condition thereof prior to the filing date of this application. See, for example, Stoner and Nugara, et al. ("A Convenient Reduction of Thienyl Alcohols", Sulfur Letters, Vol. 14(6), pp. 269-273, 1992), as well as the references cited therein. The amount range (2.0 to 6.0 equivalent) of TMSI and the temperature range were known at the filing date of the application.

Furthermore, as explained by the Federal Circuit, the specification need not describe or enable the application to a lay person, rather need only describe the invention to one of ordinary skill in the art. (See *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 56 USPQ2d 1332, 1336 (Fed. Cir. 2000)) Therefore, also as found in *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584, 39 USPQ2d 1573, 1578-79:

Prior art references may be indicative of what all those skilled in the art generally believe a certain term means ... [and] can often help to demonstrate how a disputed term is used by those skilled in the art.

Therefore, the interpretation of the same or similar claim terminology in the prior art may be used in determining what one of ordinary skill in the art would have understood the patent disclosures to teach with respect to the enablement

requirement. See also *In re Cortright*, 165 F.3d, 1353, 49 USPQ2d 1464 (Fed. Cir. 1999) in which the prior art understanding of terminology used in the patent claims was used to determine that the claimed invention was in fact enabled by the patent application disclosure. Therefore, reconsideration of all the claims is respectfully requested.

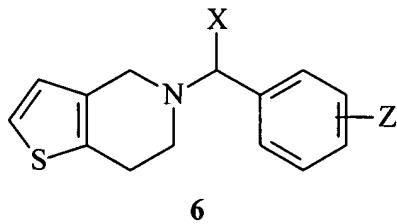
As indicated at paragraph (c) of the Examiner's Office Action at page 3, rate of addition and reaction temperature have been dealt with in Applicant's application and again the Examiner is reminded that in Stoner there is clear teaching of how one should add TMSI, i.e. the rate of addition, as well as the reaction temperature. Stoner provides at page 11049 and 11050 that slow addition over an hour to a 0°C solution produces only a trace of impurity. In Applicant's Example 8, Applicant provides the addition of TMSI at 0 to 5°C where the addition is carried out while maintaining the 0 to 5°C temperature. A person skilled in the art in reading Example 8 would appreciate this is what is occurring. Since after the addition is complete, the mixture is warmed to room temperature and stirred for two hours. This statement indicates that the addition must occur at 0 to 5°C reaction temperature. This is in line with Stoner's teaching that the reaction conditions must be kept below 20°C. Therefore, it is clear from Example 8 that the rate of addition is slow in Example 8, in order to maintain the temperature at 0 and 5°C.

In respect of the amount or concentration of TMSI used in dehydroxylation, again the Examiner is directed to Stoner which provides a minimum of 2.0 equivalents. Furthermore, at page 11055 of the Stoner reference there is a general procedure for large scale reduction of biaryl methanols with TMSI, where there is provided 4.36 equivalents, and at page 11057 there is provided small scale reduction with TMSI where the amount of TMSI is provided as 4.64 equivalents of TMSI. Therefore, a person skilled in the art would know in light of Stoner article in Applicant's application that there is no undue experimentation required in the use of TMSI in Applicant's process since Stoner provides detailed teaching on how TMSI is to be

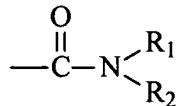
used as a reducing agent, and Applicant is not required to provide teaching of the prior art as indicated in the case law above.

Furthermore, the Examiner is reminded that the essence of Applicant's invention is not the amount or concentration of TMSI but the use of TMSI in the novel process which results in a product which is of high purity and which does not suffer from the disadvantages of the prior art, namely in the sense that Applicant's invention includes other functionalities (methyl ester) and also Applicant's novel process does not observe the impurities found in the prior art encountered with  $\text{SnCl}_2/\text{HCl}$  reagents in the work up in isolation of the product (see page 2, paragraph 6 through to page 3, paragraph 7 of Applicant's application as filed). Applicant's invention includes,

1. A process for the preparation of tetrahydrothieno[3,2-c]pyridine compound of formula 6:

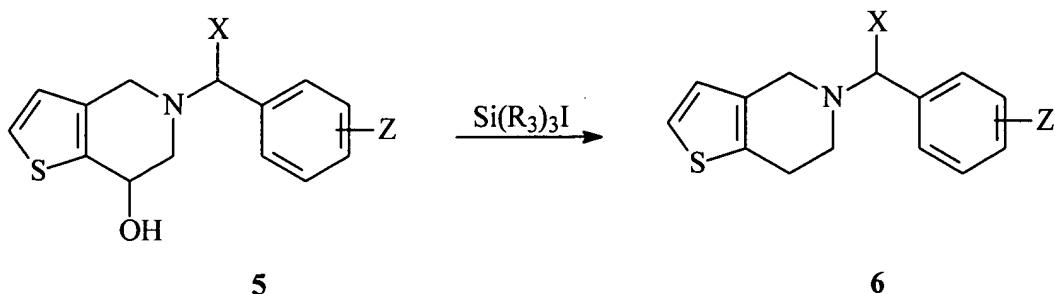


or their pharmaceutically acceptable salts, wherein the meaning of X is carboxyl, alkoxy carbonyl, aryloxycarbonyl, or carbamoyl of formula



wherein  $\text{R}_1$  and  $\text{R}_2$  can be individually or simultaneously hydrogen, or alkyl; Z can be hydrogen, halogen, alkyl, aryl, aryloxy or alkoxy group, the process comprising conducting a dehydroxylation reaction on the compound of formula 5 in order to obtain a compound of formula 6, wherein said dehydroxylation

reaction is effected by iodosilane represented by the formula  $\text{Si}(\text{R}_3)_3\text{I}$ , wherein  $\text{R}_3$  is selected from an alkyl, alkenyl, alkynyl, or aromatic group.



Furthermore, the Examiner has taken the position that there is no motivation to modify the prior art process alone or in combination to arrive at the instant invention, and therefore clearly shows that there is no prior art which discloses Applicant's novel process.

Therefore, Applicant respectfully submits all the rejections in the Examiner's Office Action of June 21, 2005, are overcome by the amendments and the arguments herein, and the Application is now in condition for allowance, and the same is solicited at the Examiner's earliest convenience.

Should the Examiner require any further discussion or clarification, the Examiner is invited to contact Applicant's Agent, Ivor M. Hughes at (905) 771-6414 and ask for Samuel Tekie.

Respectfully submitted,

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Agent for the Applicant

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Enclosures